

# Quadrivalent Human Papillomavirus (HPV) Vaccine Update

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION



# Overview

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- Recommendations
- Vaccines for Children (VFC)
- Vaccine distribution
- Post-licensure safety data
- Monitoring vaccine impact
- School mandates

# Quadrivalent HPV Vaccine Recommendations

- ACIP recommendation: June 2006
- Provisional recommendations posted on web: July 2006  
[www.cdc.gov/nip/recs/provisional\\_rec/hpv.pdf](http://www.cdc.gov/nip/recs/provisional_rec/hpv.pdf)
- ACIP statement to be published April 2007

# Vaccines for Children (VFC)

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- VFC resolution: June 2006
- Federal contract: October 2006
- Excise tax added, current contract price \$96.76/dose

# Quadrivalent HPV Vaccine Doses Distributed in the US\*

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- 2.1M doses through December 31, 2006  
~ 40% purchased with public sector funds

\* Data provided by manufacturer

# **Preliminary Post-licensure Safety Data**

# Vaccine Adverse Event Reporting System (VAERS): Quadrivalent HPV Vaccine through January 2007

**Total reported**      **N = 542**

**Sex**

Female      99%

Males      <1%

**Age (yrs)**

<9      1%

9-12      7%

13-18      47%

19-26      38%

>26      6%

Percents based on those with known data

# VAERS Data for HPV Vaccine: 5 most frequently reported symptoms (total reports = 542)

Injection site pain 18%

Dizziness 11%

Syncope 11%

Fever 9%

Nausea 9%

Each report may be coded with more than one symptom  
Coding system changed from COSTART to MedDRA, Jan 2007



# VAERS Data for Quadrivalent HPV Vaccine

## Guillain-Barre - 3 cases

- Vaccines and onset post HPV vaccine
  - 1 HPV vaccine - unknown
  - 2 HPV vaccine and MCV4 - 13 days and 9 days

## Facial Palsy - 3 cases

- Vaccines and onset post HPV vaccine
  - 1 HPV vaccine - 1 day
  - 1 HPV vaccine and live attenuated influenza - 1 day
  - 1 HPV vaccine and inactivated influenza - 1 day

# Vaccine in Pregnancy Registry

Managed by Merck and Co, Inc.

- 44 exposures (43 US, 1 Canada)
- 38 enrolled in the registry
- Outcomes - 4 known
  - 2 elective abortion
  - 2 spontaneous abortion

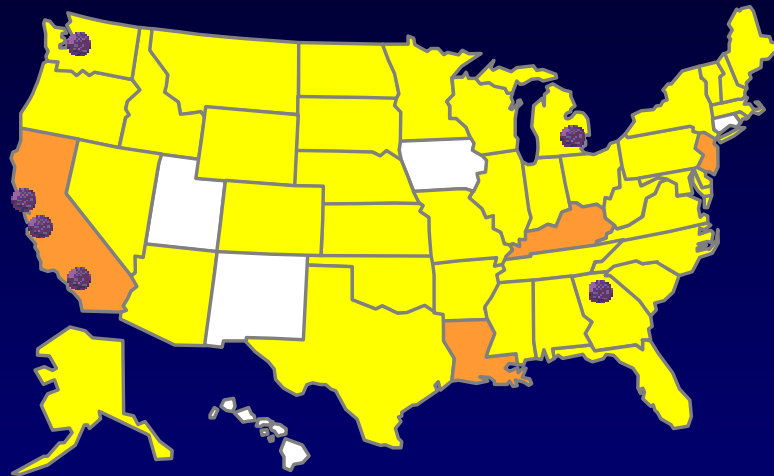
Through Jan 10, 2007

# Monitoring Impact of HPV Vaccination

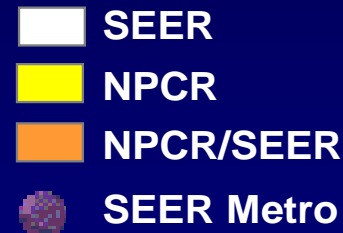
- Cervical cancer and other HPV-related cancers
- HPV prevalence
- Cervical intraepithelial neoplasia (CIN)
- Genital warts

# Cancer Surveillance

## National Program of Cancer Registries (NPCR) and Surveillance Epidemiology and End Results (SEER)



- ◆ SEER since 1973
- ◆ NPCR Since 1995
- ◆ 96% population coverage



# Monitoring Impact of HPV Vaccination in the United States

- Cervical cancer
  - Cancer registries
  - HPV typing to be initiated at several sites
- Type-specific HPV prevalence
  - NHANES - self collected vaginal swabs added in 2002
- CIN 2/3
  - Supplemental data collection in Vaccine Safety Datalink (VSD)
  - Administrative databases
  - New sentinel projects to be initiated
- Genital warts
  - STD clinics
  - Administrative databases
  - Other

# School Immunization Mandates

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>18 states have introduced legislation for school entry requirements

Texas - executive order for middle school requirement

# School Immunization Mandates

## Association of Immunization Managers (AIM) statement:

“School and child care immunization requirements must be used sparingly, approached cautiously, and considered only after an appropriate vaccine implementation period. This vaccine implementation period is critical to ensure that the necessary elements are in place to support a school/child care requirement, including .....

[www.immunizationmanagers.org/pdfs/SchoolrequirementsFINAL.pdf](http://www.immunizationmanagers.org/pdfs/SchoolrequirementsFINAL.pdf)

# AIM Statement (continued)

- Coverage for the vaccine in private health insurance plans
- Sufficient funding to purchase the vaccine
- Physician/provider support for the vaccine
- Public acceptance of the vaccine
- Stable and adequate vaccine supply
- Addition of vaccine to immunization information systems (registries)
- Adequate data to assure vaccine safety
- Significant uptake in the recommended population to reduce the compliance burden on the school/child care system



# ACIP HPV Vaccine Workgroup Plans

- Review data
  - bivalent HPV vaccine
  - quadrivalent HPV vaccine
  - HPV epidemiology
  - cost effectiveness
- Develop recommendation options for bivalent HPV vaccine
- Revise ACIP statement as needed

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